K041039

JUL 2 0 2004

510(k) SUMMARY

Name of 510(k) sponsor:	Genosis Ltd.
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Contact information:	Paul Bateman President & CEO Genosis Ltd. Telephone: (44) 208 408 5246 Fax: (44) 208 408 5432 E-mail: paul_bt@genosis.com
Date summary prepared:	June 25, 2004
Proprietary name of device:	Fertell Male Fertility Test
Generic/classification name:	Device, Semen Analysis
Product code (classification):	GKZ, Class II

Legally Marketed Predicate Devices:

Penetrak Cervical Mucus Penetration Test (K821186)
FertilMARQ Test kit (K011679)
Hamilton Thorne IVOS (K920179)
Humagen Semen Analysis Kit (K915229)

Device Description and Technological Characteristics:

The Fertell Male Fertility Test measures the concentration of progressively motile sperm in a fresh semen sample. The test is performed between two and seven days after the last ejaculation.

Semen is collected directly into a custom design collection container and allowed to liquefy for 30 minutes. A test unit is then positioned onto the liquefied sample and the pressing of a button releases a solution of sodium hyaluronate buffer solution over the semen sample and starts heating the fluid to 37°C. Motile sperm swim-up through the sodium hyaluronate for 30 minutes before a valve is opened, by turning a knob, allowing the buffer solution, and motile sperm present, to flow along a capillary channel. Anti-CD59 monoclonal antibody that is conjugated with colloidal gold is released from an absorbent pad in the channel and reacts with the sperm forming an immunocomplex of gold-labeled sperm. The fluid containing this complex flows onto a nitrocellulose strip where the gold-labeled sperm are trapped, forming a red line. Unreacted conjugate is washed from the strip by the flow of excess buffer.

Turning the knob back to its original position closes the valve and reveals the test result. The appearance of a clear red line (test result) indicates motile sperm in the semen sample at a concentration of ≥10M/mL. This level is indicative of normally expected motile sperm concentrations.

The device has a microprocessor to control internal fluid temperature at 37° C and provide user prompts by an LED that changes state at the end of each timed activity. A control line is present on the nitrocellulose test strip to confirm to the user that the test has functioned correctly.

Intended Use

The Fertell Male Fertility Test is intended to measure motile sperm in semen as an adjunctive screen of male fertility for home use.

Testing

The following performance evaluations were conducted with the Fertell Male Fertility Test: clinical (i.e., consumer) studies (consumer field evaluations, lay users versus professionals); in-house method comparison study versus predicate; laboratory evaluations (specificity, reproducibility, result stability, robustness to timings, and influence of ambient temperature); and stability studies.

The objective of the consumer field evaluation was to demonstrate that lay users can reliably perform the test in their home environment following the instructions provided in the package insert and other labeling (box labeling and, for some users, a supplementary instruction sheet), without confusion, complications, or procedural difficulties (i.e., validation of the adequacy of the Instructions for Use). The studies included a questionnaire to obtain feedback from lay users on various aspects of performing the test. A total of 433 questionnaires were received from the three sites. Of the 6495 responses (433 subjects x 15 questions), 6160 were correct, 335 were incorrect or no response. This demonstrate that the Fertell Male Fertility Test could be accurately performed by a general public consumer population in the home environment, the correct response level was 94.8%.

The objective of the Lay Users vs. Professionals study was to demonstrate equivalence between the lay user and professional results. Each lay user was asked to attend the trial site where they provided a semen sample and performed the Fertell Male Fertility Test following the instructions provided in the package insert and other labeling (box labeling and, for some users, a supplementary instruction sheet). On completion of the test, the lay user and a professional read the test result independently, without either having knowledge of the other's result and recorded their interpretation of the result on separate record sheets. The lay users were not given any assistance in the performance of the test. The results from 121 subjects, expressed as percent accuracy based on test efficiency according to NCCLS guidelines (GP14-A, June 1996), show a percent accuracy between the lay user and the professional of 95.0%.

The objective of the Method Comparison Study was to demonstrate equivalence between the Fertell Male Fertility Test and the predicate method (a laboratory run, computer-aided sperm analysis system, CASA, the Hamilton Thorne IVOS system). A sperm migration test (modified Kremer test) was also used, as a secondary predicate method. Subjects were asked to attend the

trial site and provide a semen sample into a laboratory collection container. Testing of the sample by the two predicate methods and by the Fertell Male Fertility Test was performed by a laboratory professional. The results from 140 subjects expressed as percent accuracy, based on test efficiency according to NCCLS guidelines (GP14-A, June 1996), show a percent accuracy against the predicate method of 95.7%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Genosis Ltd.
c/o Sharon A. Segal, Ph.D., Director, Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, NW
Washington, DC. 20004

JUN 15 2012

Re: k041039
Trade/Device Name: Fertell Male Fertility Test
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: April; 21, 2004
Received: May 11, 2004

Dear Dr. Segal:

This letter corrects our substantially equivalent letter of July 20, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Genosis Ltd.

510(k) Number: K041039

Device Name: Fertell Male Fertility Test

Indications for Use:

The Fertell Male Fertility Test is intended to measure motile sperm in semen as an adjunctive screen of male fertility for over-the-counter (OTC) home use.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ or Over-the Counter Use ✓

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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